DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 4, 2007

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 07-05

William A. Karcher, President
Mikayle L. Karcher, Vice President/Secretary-Treasurer
Winchester Bay Seafood, Inc.
182 Bay Front Loop
Winchester Bay, Oregon 97467

WARNING LETTER

On August 30 and 31, 2006, we inspected your low-acid canned food processing facility, located at 82 Bay Front Loop, Winchester Bay, Oregon. We found that you have serious deviations from the Low-acid Canned Food (LACF) regulations (21 CFR Parts 108 and 113). Failure to comply with all of the requirements of 21 CFR 108.35 and the mandatory portions of Part 113 constitutes a prima facie basis for the immediate application of the Emergency Permit control provisions of Section 404 of the Federal Food, Drug and Cosmetic Act (the Act). In addition, such failure renders your low-acid canned food adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly, your canned tuna is adulterated in that it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You can find the Act and the Low-acid Canned Food regulations through links in FDA's home page at http:/www.fda.gov.

Your significant violations were as follows:

1. When a vertical retort deviates from the specifications prescribed by 21 CFR 113.40(a)(12)(ii)(a) and (b), the processor must keep on file evidence in the form of heat distribution data that the installations and operating procedures used accomplish adequate venting of air, to comply with 21 CFR 113.40(a)(12)(iii). Both your number 1 retort and number 2 retort are configured with top side steam inlets and bottom vents that deviate from the specifications prescribed by 21 CFR 113.40(a)(12)(ii)(a)

and (b); and you have no heat distribution data on file demonstrating these retorts are adequately vented.

2. Your retort bleeders, except those for thermometer wells, must be one-eighth inch or larger and must be wide open during the entire process, including the come-up-time, to comply with 21 CFR 113.40(a)(8). However, the bleeder located opposite the steam inlet on your Retort 2 was restricted by a bent wire clothes hanger, which was inserted directly into the 1/8" bleeder opening without evidence in the form of heat distribution data that this configuration accomplishes adequate removal of air and circulation of steam within the retort.

3. When a manifold header is connecting vents or manifolds from several still retorts, it must lead to the atmosphere, to comply with 21 CFR 113.40(a)(12). However, the manifold header connecting vents or manifolds from your retorts was not vented to the atmosphere. Specifically, a one inch diameter pipe connecting the vent pipes from Retort #1 and Retort #2, extending to the outside of the building and opening above the ground, was observed to have a piece of pipe insulation on the outside of the pipe that had slipped down below the pipe opening and rested against the ground, thereby extending the pipe to the ground and restricting the flow of steam, air, and water from the venting retorts.

4. Your firm's retorts must be equipped with at least one mercury-in-glass thermometer whose divisions are easily readable to 1 °F, to comply with 21 CFR 113.40(a)(1). However, the mercury-in-glass thermometer on your Retort #2 was not easily readable due to the fact that the inner cover of the thermometer exhibited excessive condensation during thermal processing, making accurate observation of the column difficult.

We also found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR Parts 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your histamine-forming fish including albacore are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation, and the Fish and Fishery Products

Hazards and Controls Guidance through links in FDA's home page at www.fda.gov.

5. You must monitor sanitation conditions and practices during processing with sufficient frequency to ensure compliance with current good manufacturing practice requirements in 21 CFR Part 110, to comply with 21 CFR 123.11(b). However, your firm did not monitor protection of food, food packaging material, and food contact surfaces from adulteration, and exclusion of pests with sufficient frequency to ensure compliance with the current good manufacturing practice requirements in 21 CFR Part 110 as evidenced by:
    - More than ten live flies were observed flying and crawling in and on processing surfaces in the fish cutting area and the canning/processing area.
    - Two loading doors remained open to the fish cutting area. The screen at the open window in the canning/processing area is damaged with a gap to the outside. Employees were cutting tuna at the time of this observation.
    - Two employees cutting tuna in the fish cutting area and one employee in the canning/processing area were wearing hats with long unrestrained hair extending beyond the hats. One employee cutting tuna in the fish cutting area had a long unrestrained beard.
    - One set of unshielded fluorescent lights (four bulbs) is located above a tote of iced fish and an open tote of processing ice in the fish cutting area.

6. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b) and (c)(7). However, your firm did not record monitoring observations at the receiving critical control point to control histamines listed in your HACCP plan for Fresh/Frozen Albacore Tuna. Specifically, you have not maintained any records of the monitoring of the internal temperature of the Albacore tuna at receipt or of your sensory evaluation of the tuna for decomposition at receipt. You also have not maintained records of monitoring the onboard vessel monitoring records.

7. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for Fresh/Frozen Albacore Tuna does not list the critical control point of refrigerated storage for controlling the food safety hazard of histamine formation.

8. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for Fresh/Frozen Albacore Tuna lists a critical limit at the receiving critical control point that is not adequate for controlling the food safety hazard of histamine formation. Specifically, it does not list critical limits for product temperature during onboard storage after cooling and the cooling time does not refer to the time of death.

9. You must have a HACCP plan that lists monitoring procedures, and frequency thereof, for each critical control point, in order to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Fresh/Frozen Albacore Tuna lists monitoring frequencies for on-board cooling, internal temperature, and decomposition (See Hazard Guide) at the receiving critical control point that are not adequate for controlling the food safety hazard of histamine formation.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s), enjoin your firm from operating, and/or issue an Order of Need to Obtain and Hold a Temporary Emergency Permit.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the LACF regulations (21 CFR Parts 108 and 113), the seafood HACCP regulation (21 CFR Part 123), and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your written reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding this letter, please contact Mr. Donovan at (425) 483-4906.

Sincerely,

Charles M. Breen
District Director

Enclosure:
Copy of FDA 483

cc: OSDA, with disclosure statement